

Food and Drug Administration Cincinnati District Office Central Region 6751 Steger Drive Cincinnati, OH 45237-3097 Telephone: (513) 679-2700

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WARNING LETTER CIN-04-20950

VIA FEDERAL EXPRESS

April 16, 2004

Michael Ward, President CSX Transportation 500 Water Street Jacksonville, FL 32202

Dear Mr. Ward:

This letter serves as your formal notification that the U.S Food and Drug Administration (FDA) has classified the Watering Point at your rail service support facility located at Russell Terminal CSX Big Four, Russell, Kentucky, as "Provisional" for interstate carrier use.

On January 13-14, 2004, a Food and Drug Administration investigator conducted an inspection of your Watering Point. The inspection revealed significant deviations from the Interstate Conveyance Sanitation regulations, 21 CFR 1250, issued under the authority of the Public Health Service Act. All servicing area piping systems, hydrants, taps, faucets, hoses, buckets, and other appurtenances necessary for delivery of drinking and culinary water to a conveyance shall be designed, constructed, maintained, and operated in such a manner as to prevent contamination of the water, to comply with 21 CFR 1250.67. However, the inspection revealed that:

- All 12 water transfer hoses used to service trains and were not capped at the end used to connect to the hydrant.
- At least half of these hoses had corrosion on the interior of the metal connectors.
- One of the hydrants used to service train was not capped and was leaking water.
- Hoses in all six storage cabinets were exposed to rust from the bottom of the cabinets.
- The easternmost four out of the six hydrant cabinets used to service train appeared to contain bird nesting materials and other debris and two of these four hydrant cabinets were damaged and exposed to the environment.

• All six of the cabinet doors were unsecured and open.

A written list of these deficiencies was issued to the inspection.

The deficiencies found at your servicing facility could contribute to the spread of communicable diseases. Based on the inspectional findings, we are classifying your facility as "Provisional" for interstate carrier use. A "Provisional" classification means that the facility may continue to operate; however, correction of deficiencies must be made by the time the facility is re-inspected. If significant corrections are not made by the time of the next inspection, the facility will be reclassified as "Not Approved" for carrier use. A classification of "Not Approved" prohibits the use of your watering services by interstate conveyances until the deficiencies have been corrected and the facility has been re-inspected by FDA.

You should notify this office in writing within fifteen (15) working days of the receipt of this letter of the steps you have taken to address the deficiencies. Your response should include an explanation of each step being taken to correct the deficiencies and prevent their recurrence. Include copies of any available documentation demonstrating that corrections have already been made.

Your response should be directed to the attention of Stephen J. Rabe, Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237 (513) 679-2700 extension 163.

Sincerely,

Carol A. Heppe
District Director
Cincinnati District

cc: Clayton Pape, Public Health Coordinator

Amtrak Central Division